Minutes
Meeting between FDA and ASRM
Regarding Donor Suitability Issues

February 10, 2000

NIH, Building 29B, Conference Room A

Present:

FDA: CBER: Kathryn Zoon, Ruth Solomon, Paula McKeever, Jay Epstein, Jay Siegel, Marty Wells, Antonio Pereira; CDRH: Elisa Harvey, Jean Fourcroy; OCC: Kate Cook, Diane Maloney

External (ASRM): Jeff Chang, President, Mike Soules, President Elect, Bud Keye, Vice President, Robert Rebar, Assoc. Executive Director, Ben Younger, Executive Director, Sean Tipton, Public Affairs Director, Larry Lipshultz, A.F. Hawsey

ASRM requested this meeting with FDA to review the ASRM comments to the public docket as they related to reproductive tissue and practices under the proposed regulation, "Suitability Determination for Donors of Human Cellular and Tissue-Based Products", published on September 30, 1999.

FDA began the meeting by outlining certain provisions in the proposed rule that ASRM addressed in its comments to the docket. Specifically, the proposed rule does not directly indicate that quarantine of oocytes and embryos would be required. Rather it states (1271.60 (a)) and further explains in the preamble that cells or tissue that can reliably be stored and maintain function and integrity during storage shall be frozen and quarantined for 6 months. However, a sentence in the rule's economic analysis indicates that oocyte and embryo quarantine might be required. FDA noted that another comment to the docket from the Mayo Clinic provided non-validated information that embryo freezing does not significantly lower the viability or pregnancy success of the embryo. FDA also pointed out that sexually intimate couples will not be required to be screened and tested, and therefore the quarantine provision does not apply to them.

FDA indicated that at this time they disagree with ASRM's assertion that washed sperm do not pose the same disease risks as unwashed semen. There is a need for sufficient data demonstrating that the washing procedure has been validated to remove infectious agents. CDC is currently examining such data for HIV transmission by washed semen in the situation of discordant couples.

ASRM requested that FDA define what it considers "reliably stored" to mean. They asked if a cut off will be established such as viability 20 percent of the time or using fresh embryo transfer pregnancy rates as an indicator? FDA responded that they would provide examples in the preamble to the final rule. Guidance documents could provide

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such technical information, which could change as the science evolves. FDA could also address this issue in future public scientific meetings to discuss storage data.

Discussion followed regarding which tissues FDA considered leukocyte-rich and thereby needing donor testing for HTLV I and II, and CMV under 1271.85 (b). The preamble states that FDA considers hematopoietic stem cells and semen leukocyte-rich. FDA indicated that oocytes and embryos are not considered leukocyte-rich. ASRM noted that there is no known evidence of transmission of HTLV I and II by semen and the incidence of infection in the US is low. FDA explained that the risk of transmission varies depending upon the degree of immunosuppression of the recipient.

ASRM stated that the requirement (1271.80 (b)) for donor testing within 7 days of tissue recovery is incompatible with the recruitment and treatment protocols currently used for oocyte donors. These donors are tested before they are selected and matched with a recipient. The donor and the recipient are then subjected to two to three weeks of drug treatments. Requiring a second test before donation and possibly rejecting a donor at that time would cause undue mental, physical and financial hardship to the recipient especially in light of the fact that there is no evidence to indicate that oocytes are capable of transmitting disease. ASRM stated that the seroconversion rate of individuals in a sperm donation program is exceedingly low. FDA requested data to document this. ASRM also finds problematic the fact that if the sexually intimate donors of the sperm and oocytes had not been tested, and if some of the resultant embryos were frozen for later use, they could not be donated to another recipient. Though there are few requests for donated embryos, the possibility of permitting testing of stored serum from both donors at the time of donation for later testing was discussed. FDA indicated that they would take these issues into consideration when drafting the final rule.